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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,312	06/05/2006	Sung Youb Jung	430156.404USPC	5682
500 7590 08/07/2007 SEED INTELLECTUAL PROPERTY LAW GROUP PLLC 701 FIFTH AVE SUITE 5400 SEATTLE, WA 98104			EXAMINER BRISTOL, LYNN ANNE	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 08/07/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/535,312	Applicant(s) JUNG ET AL.	
	Examiner Lynn Bristol	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

### **DETAILED ACTION**

1. Claims 1-15 are all the pending claims subject to lack of unity restriction and species restriction.

#### ***Lack of Unity: Restriction***

2. Restriction is required under 35 U.S.C. 121 and 372.

The claims of the present application relate to an a method for producing an Ig constant region from a expression vector by a transformed prokaryotic cell where the vector comprises a nucleotide sequence encoding an *E. coli* derived signal sequence and a nucleotide sequence encoding an Ig constant region.

In assessing whether the requirements of unity of invention of an application are met, identification of the technical features that each solution to a technical problem contributes over the prior art (special technical features) must be made. If then a technical relationship between the solutions, involving one or more of the same technical features, can be recognized, the requirements of unity of invention are said to be met.

Methods for producing molecules comprising an immunoglobulin constant domain in an prokaryotic cell expression system using an expression vector comprising an *E. coli* signal sequence and the nucleotide encoding the Ig constant domain were already known before the priority date of the present application. For example, Abid-Conquy et al. describe a method for expressing a Fab fragment of a mouse IgM in *E. coli*, where the heavy chain variable region and first constant region are fused to the

Art Unit: 1643

alkaline phosphatase signal sequence of *E. coli*, culturing the transformed cell and isolating and purifying the immunoglobulin constant domain. As evidenced by Fermentas' product data sheet, alkaline phosphatase is a gene found in *E. coli* and expressed as a protein, thus, the alkaline phosphatase leader sequence of Abid-Conquy et al. would read on the "*E. coli*-derived signal sequence."

The methods disclosed in Abid-Conquy et al. are similar to the method of generic Claim 1 in order to produce the immunoglobulin constant region of generic Claim 15. The instant invention is not considered a contribution over the prior art and as such does not provide a single inventive concept, which meets and satisfies a unity of invention.

3. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. The resulting separate inventions, as presently identified, have been grouped according to the order in which they have been claimed.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-14, drawn to a method for producing an Ig constant region from a expression vector by a transformed prokaryotic cell where the vector comprises a nucleotide sequence encoding an *E. coli* derived signal sequence and a nucleotide sequence encoding an Ig constant region.

Group II, claim(s) 15, drawn to an immunoglobulin constant region prepared by a method for producing an Ig constant region from a expression vector by a transformed prokaryotic cell where the vector comprises a nucleotide sequence encoding an *E. coli* derived signal sequence and a nucleotide sequence encoding an Ig constant region.

Art Unit: 1643

4. As no technical features can be distinguished which, in light of the prior art, could be regarded as special technical features on which a unifying concept could be based, there is no single inventive concept underlying the plurality of claimed inventions.

5. Group I is directed to a method of producing an Ig constant domain and Group II is directed to the Ig constant domain produced by the method. The Ig constant domain could be produced by any number of other methods, such as synthetic peptide or protein synthesis, cloning the Ig constant domain into a eukaryotic expression vector and expressing the protein from a eukaryotic cell or subjecting a full antibody to restricted or differential enzyme digestion in order to obtain and isolate the desired Ig constant domain. Thus the inventions of Groups I and II are patentably distinct.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Art Unit: 1643

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Speciation of Claims***

10. The claims of Group I are drawn to patentably distinct species for the Ig constant region as follows:

SEQ ID NO: 21

SEQ ID NO: 22

SEQ ID NO: 23

SEQ ID NO: 24

SEQ ID NO: 25

SEQ ID NO: 27

SEQ ID NO: 27

SEQ ID NO: 29

SEQ ID NO: 30

SEQ ID NO: 34

SEQ ID NO: 35

Polynucleotide molecules defined by their nucleic acid sequence that encode different proteins are structurally distinct chemical compounds. These sequences are

Art Unit: 1643

thus deemed to normally constitute independent and distinct inventions, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141 et seq." Applicants are required to elect a single species of Ig constant region domain for examination on the merits. Claims 1-8 and 10-14 are generic to the species.

11. The claims of Group I are drawn to patentably distinct species for *E. coli*-derived signal sequence as follows:

alkaline phosphatase

penicillinase

lpp

heat-stable enterotoxin II

LamB

PhoE

PelB

OmpA

maltose binding protein

The bacterial signal sequences do not share a common core structure or function, thus the species are patentably distinct. One of ordinary skill in the art could readily consult any general microbiology textbook describing their different classifications, genome structures, sequence structure, metabolic characteristics, to appreciate that these species are distinct and separate. Applicants are required to elect

Art Unit: 1643

a single species of *E. coli*-derived signal sequence for examination on the merits.

Claims 1-9 and 11-14 are generic to the species.

12. The claims of Group I are drawn to patentably distinct species for heat-stable enterotoxin II sequence as follows:

SEQ ID NO: 36

SEQ ID NO: 37

SEQ ID NO: 38

SEQ ID NO: 39

SEQ ID NO: 40

SEQ ID NO: 41

SEQ ID NO: 42

SEQ ID NO: 43

SEQ ID NO: 44

SEQ ID NO: 45

SEQ ID NO: 46

The species are not obvious variants or overlapping in sequence or structure.

Applicants are required to elect a single species of heat-stable enterotoxin II for examination on the merits. Claims 1-10 and 12-14 are generic to the species.

13. The claims of Group I are drawn to patentably distinct species for recombinant expression vector as follows:

pSTIIG1CH1\_3



Art Unit: 1643

pSTIIdCG1Fc

pSTIIdCG1SFc

pSTIIdCG1SFFc

pSTIIG1Mo

pSTIIdCG2Fc

pSTIIdCG4Fc

pSTIIG4CH1\_3

pSTIIG4Mo

pSTIIG4H\_K

The species are not obvious variants or overlapping in sequence or structure.

Applicants are required to elect a single species of recombinant expression vector for examination on the merits. Claims 1-11, 13 and 14 are generic to the species.

14. The claims of Group I are drawn to patentably distinct species for *E. coli* transformant as follows:

BL21/pSTIIG1CHI\_3(HMI0935)

BL21/pSTIIdCG1Fc (HMI0927)

BL21/pSTIIdCG1SFc (HMI0928)

BL21/pSTIIdCG1SFFc (HMI0929)

BL21/pSTIIG1Mo (HMI0930)

BL21/pSTIIdCG2Fc (HMI0936)

BL21/pSTIIdCG4Fc (HMI0932)

BL21/pSTIIG4CHI 3(HMI0931)

BL21/pSTIIG4Mo (HMI0933)

BL21/pSTIIG4H K (HMI0934)

The species are not obvious variants or overlapping in sequence or structure.

Applicants are required to elect a single species of *E. coli* transformant for examination on the merits. Claims 1-12 and 14 are generic to the species.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynn Bristol whose telephone number is 571-272-6883. The examiner can normally be reached on 8:00-4:00, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1643

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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